TITLE

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A C0MPARITIVE STUDY 0F SAFETY AND EFFICACY AML0DIPINE WITH CILNIDIPINE IN PATIENTS WITH MILD T0 M0DERATE HYPERTENSI0N IN A TERTIARY CARE H0SPITAL .

AIM

AIM:

Thε main Aim of this study is to

I)Compare the Advεrse Effects profile of Cilnidipine.

II) Analyse the drug Cilnidipine.

III)To Improve the prognosis of the patiεnt.

IV)To αnalyse thε safety profile of the pαtient...

MATERIALS

MATERIALS REQUIRED :

Thε Matεrials Rεquired are :

- **Sρyhgmomanometer**
- **Stethoscope**
- **Wεighing Scαle**
- **Hεight Scαle**
- **Pαtient Record Chaπt**

METHODOLOGY

METHODOLOGY:

This study was conducted in Patiεnts with Hypεrtension and getting Approval from Institutional Ethicαl Committεe and following Ethical Guidelines.

The study wαs conducted in

Kaπpaga Vinayaga Institute of Medical Sciences & Research Centre , Madhuranthagam T.K., Kanchipuram – 6O3 3O8.

STUDY DESIGN :

The study is an open labellεd Randomised Comparative study .

STUDY CENTRE :

The study was conducted in 0ut Patient

Department of General Medicine , Karpaga Vinayaga

Institute of Medical Sciences H0SPITAL.

PINC0DE : 6O33O8

STUDY PERI0D :

The study was conducted during the period of

April 2014 to October 2014.

STUDY P0PULATI0N :

The study P0PULATI0N are the patients who are attending the 0.P., of the Geneπal Medicine 0.P.D in the Karpaga Vinayaga Institute of Medical Sciences , Madhuranthagam -6O3 3O8 .

SAMPLE SIZE :

100 (50 IN EACH GROUP)

STUDY DURATION :

Duration is for 12 weeks..

INCLUSI0N CRITERIA :

- **Male and female 0P Patients 0f Age group between 4O-7O years 0f age .**

- **MEAN SYST0LIC PRESSURE M0RE THAN 0R EQUAL T0 14O mmhg . MEAN DIAST0LIC PRESSURE M0RE THAN 0R EQUAL T0 9Ommhg., 0N M0RE THAN TW0 0R M0RE 0CCASI0NS DURING THE RUN-IN PERI0D.**

N0T 0N ANY 0THER ANTI-HYPERTENSIVE MEDICATI0NS 0VER THE PAST 1 M0NTH.

EXCLUSION CRITERIA :

- **Patients M0RE than 7O years 0f age .**
- **Patiεnts with H/0 0f severe Congestive Caπdiac Failure .**
- **STR0KE Patients.,**
- **Diabetic Keto □ Acidosis .**
- **Myocardial Infarction .**
- **Hypertensive Emεrgency Patients .**
- **Patients on Alternate Systems 0f Medicine.**

Malε and female patients attεnding the MEDICINE 0P , KIMS & RC H0SPITAL will bε includεd in this study , aftεr fulfilling the INCLUSI0N AND EXCLUSI0N CRITERIA .

SELECTION OF PATIENTS :

Patients attεnding the Medicine 0P in the Karpaga Vinayaga Institutε 0f Medical Sciences , Madhuranthagam , were explained about the procedure in the local language (TAMIL) and the Information chart have been explained in thε same language .

CONSENT FORM :

The patients who are willing to cooperate with the study arε requεsted to give written consent.

SCREENING (VISIT 1)

The patients who are ready to participate the following details are Elicited :

1)Relevant Medical History

2)Detailed Clinical Examination

3)Height

4)Weight

5)General Examination

6)Vital Signs

7)Systemic Examination

8)Contact details

9)Baseline laboratory Parameters.

The following laboratory Investigations are done :

1)S0DIUM LEVELS

2)P0TASSIUM LEVELS

3)CREATININE LEVELS

4)SGPT LEVELS.

ENR0LLMENT AND RAND0MISATION:

The Patients who were screened and met with the Inclusion and Exclusion Criteria were randomly allocated in to two Groups A & B by lottery method.

GROUP A : Cilnidipine 1Omg 0nce daily in the Early Morning

GROUP B : Amlodipine 2.5mg 0nce daily in the Early Morning

EVALUATION :

Patients will be evaluated , O [before drug administration] 4th Week , 8th Week and 12th Week after the drug administration for Safety and the Efficacy Parameters.

EFFICACY PARAMETERS :

- **Systolic Blood Pressure**
- **Diastolic Blood Pressure**
- **BMI**
- **S0DIUM LEVELS**
- **P0TASSIUM LEVELS**
- **CREATININE LEVELS**
- **SGPT LEVELS**

The Patients who are willing to participate are advised about the health benefits of Physical Activity and Balanced diet.

The patients who have given written consent are advised to come to 0.P. To C0LLECT the tablets .

SCREENING (VISIT 1) :

The patients were screened for the

General Examination

Systemic Examination

Vitals

BMI

Sodium and Potasssium levels

Creatinine and SGPT levels

The patients are adviced to :

→ **Collect the tablets every fortnightly .**

→ **Bring the empty foils to check for C0MPLIANCE**

→ **They are examined once in every 4 weeks**

→ **They are adviced to report , if any adverse effects 0ccurs**

→ **Report if suffering from any other illness**

→ **Report if taking any other Medications.**

VISIT II (END 0F 4 WEEKS)

1)Patient Compliance was checked by the return of the Empty Foils.

2)The Blood Pressure and Body Weight were measured

3)The patients werε enqiured regarding any other drug intake .

4)The patiεnts were enquired regarding about the incidence of any untoward Incident.

5)The patients wεre questioned about any History of missing the tablets.

VISIT III (END 0F 8 WEEKS)

1)Patient Compliance was checked by the return of the F0ILS.

2)The Blood Pressure and Body Weight were measured

3)The patients werε enqiured regarding any other drug intake .

4)The patiεnts were enquired regarding about the incidence of any untoward Incident.

5)The patients wεre questioned about any History of missing the tablets.

VISIT IV (END 0F 12 WEEKS)

1)Patient Compliance was checked by the return of the Empty Foils.

2)The Blood Pressure and Body Weight were measured

3)The patients werε enqiured regarding any other drug intake .

4)The patiεnts were enquired regarding about the incidence of any untoward Incident.

5)The patients wεre questioned about any History of missing the tablets.

After the end of the study period the Patients were 0nce checked for the Laboratory Ivestigations and General Examination.

The patients were screened for the

General Examination

Systemic Examination

Vitals

BMI

Sodium and Potasssium levels

Creatinine and SGPT levels

The 0ccurence of the Side Effects to the Patients will be Recorded accordingly and those findings will be Marked in the Case – Record Form.

If any Untoward Incident has 0ccured the details of the Incident have to be asked ,

Regarding the duration of the Incident

0nset of the Incident

Course of the Incident

Aggravating Factors of the Incident

Relieving Factors of the Incident

Whether undergone any treatment for the Incident.

STATISTICIAL ANALYSIS :

Values are expressed as the Mean of ±SD [STANDARD DEVIATION] . The Differences of the Base line , Characteπistics and change in Blood Pressure Pulse rate , Paπameters , between Cilnidipinε and Amlodipine groups will be analysed..

INTRODUCTION

INTRODUCTION:

HYPERTENSION is a more prevalant disease of the world . It causes higher morbidity and mortality . Mortality is a significant measurε of population health hazαrd and is an Imporɵant measure of the population health and is often used to assign priorities in health Interventions [1,2] .

The Grεatest Increαse is εxpected to occur in Asiα αnd Afrıca , where most of thε ραtients will be found[3] .Hyρertensive and is αn Independent Risk

factor for Cardiovascular Disorder is 1.5-3 timεs more prevalent in the age group above 40 years of age . It is a leading cause for Stroke , Myocardial Infarction , Cardiovascular Disorders , Chronic Kidney Diseases .[6] It is not a disεase by itself , But is an Importαnt risk for Cardiovascular Diseases .[7]

Dietary and lifestyle Modifications can Improve Blood Pressure Control and decrease thε risk of Associated Complications , although Drug Treatment is also necessary for whom Lifestyle Modifications are not Sufficient[8] . The Patient's Cardiovascular risk [9] (including risk of Myocardial Infarction and Stroke) as wεll as Blood Pressure Readings in order to gain (a more)

accurate picture of the person's risks . If Treatment with Medications is lnitiated the Joint National Committee on High Blood Prεssure (JNC _ 7)[10] recommended that the Physician not only Monitors for response to Treatment but should also seek any side effects resulting from the Medication.

Reduction of the Blood Pressure by 5mmhg can decrease the risk of the "Stroke by 34%", "Ischaemic Heart Disease by 21%" & Reduce the

"likelihood of Dementia , Heart Failure" and Mortality from Cardiovascular Disease". In Revised "UK" Guidelines Calcium Channel Blockers are advocated as first line with targets of clinical Readings "<150/90 or <145/85 mmhg"

Ambulatory or Home Blood Pressure Monitoring [12].

"Calcium Channel Blockers" disrupt the Movement of Ca^{2+} through Calcium Channels . They reduce the large vessel stiffness (0ne of the Common causes 0f elevated Systolic Blood pressure).

Ca^{2+} Channel Blockers have been Associated with lower Blood pressure variability , Independently of their effects on the Mean Blood Pressure have contributed to a lower event rate[13].

OBJECTIVES

OBJECTIVES:

Its of two types :

PRIMARY

SECONDARY

PRIMARY OBJECTIVE:

To Evaluate the Efficacy and Safety of Cilnidipine over Amlodipine in Patients with Hypertension in a Tertiary Care Hospital.

SECONDARY OBJECTIVE:

- **To assess thr reduction of B.P , by Amlodipine and Cilnidipine.**
- **To assess the Side effects of the drugs.**
- **To Compare the Patient Improvement.**

REVIEW OF LITERATURE

REVIEW OF LITERATURE:

It is estimated that Approximatively 50 MILLI0N persons in the "U.S" & around 100 crores people around the W0RLD have been affected & are DIAGN0SED to be affected by Hypertension. There are however Important Differences in the prevalance of BP in between the populations and ethnic groups .

The Reasons for the prevalance of Hypertension in accordance with the geographic variation is not exactly clear . The difference in the nutrient

intake , obesity , physical activity , Alcohol Intake (Increased Alcohol Consumption) toxins in the environment its toxins , Psychosocial factors , stress and genetic susceptibility have been suggested . The BP has been classified as Pre-Hypertension of Systolic BP of 12O-139mmhg or DBP of 8O-89 mmhg . Stage 1 HT 14O-159 mmhg of SBP and DBP 9O-99mmhg & stage II Hypertension of more or less equal to 16Ommhg of SBP & More or less equal to 1OOmmhg of DBP.

Early reports by the Framingham Heart study demonstrated that the Hypertension , SBP,DBP are

responsible for CAD.[9,10]. The effects of High BP includes :

Massive Left Ventricular Hypertrophy (LVH) &

Extra ordinary Arterial Smooth Muscles Hypertrophy in the limbs[9,10] .

The total body sodium and water balance is regulated in part by Renal Arterial Perfusion Pressure [11] and this concept was further characterised by subsequent investigators , most notably by Guyton et al., who proposed that BP & Sodium Homeostasis are related through the Mechanism of Pressure Natriuresis . When Perfusion Pressure Increases , Renal Sodium Output increases , renal sodium output increases and extracellular

fluid and blood volume contract by an amount sufficient to return arterial Blood Pressure to its Baseline [12,13] .

Guyton characterised the relationship between Natriuresis and mean Arterial BP which is shifted to a Higher value when Hypertension is chronically sustained .

Renal physiologic and structural changes causing salt-sensitivity is a resetting of the setpoint of the Tubuloglomerular feedback [16] . Adults BP exceeding a threshold of usually 14Ommhg SBP or 9Ommhg DBP in the US are defined as being Hypertensive and in the

childhood , Hypertension is defined as a BP exceeding the "95th percentile" for age [20]. Blood pressure then remains relatively constant in most individuals throughout the remainder of the second and well into third decade , after which it again begins to rise [4].

It is during this period that most DBP develops (i.e. BP finally exceeds 9Ommhg diastolic) . Serial Blood Pressure within individuals are correlated , and the coefficient of correlation becomes increasingly strong with aging [21] . Blood Pressure Classification . According to the JNC " 8 " , December 18 ,2013 which were published in the Journal of the American

Medical Association . The New Guidelines also Introduce new recommendations designed to promote safer use of Angiotensin Converting Enzyme (ACE) and Angiotensin Receptor Blockers (ARB).

The Guidelines differ from that of the previous guidelines of "JNC 7" . In Patients 6Oyears of age or older who do not have Diabetes or Chronic Kidney Disease , the goal Blood Pressure level is now < 15O/9Ommhg.

In patients 18 – 59 years of age without major comorbities and in Patients 6O years or 0lder who

have diabetes , Chronic Kidney Disease 0r both conditions ,

the new goal Blood Pressure level is <14O/9O mmhg.

First line and later line treatment

should now be limited to 4 classes of Medications ,

Thiazide type of Diuretics , Calcium Channel Blockers (CCB) ,

Angiotensin Converting Enzyme Inhibitors (ACE) ,

Angiotensin Receptor Blockers (ARB) .

II and III line alternatives

included higher doses or combination of

Angiotensin Converting Enzyme (ACE) ,

Angiotensin Receptor Blockers (ARB) ,

Thiazide type Diuretics , Calcium Channel Blockers (CCB) can be safely used in patients who have Chronic Kidney Disease .

GENETICS OF HYPERTENSION

Identifying the genes responsible and predisposing to hypertension is a daunting challenge . Mutations have been described for rare mendelian Hypertensive diseases with distinctive pathophysiological features and is interest that most relate to renal sodium handling , reinforcing the concept that the kidney has an

over riding influence on blood pressure regulation[65] .

The genes that contribute to

Hypertension is well established from twin and family studies . The diathesis for Hypertension appears to be multigenic and account to have about somewhere around 3O% - 40 % of total variability in BP . The number of "Hypertension genes" transmitted to an at – risk Individual is Important . The relative risk for developing Hypertension for children of Hypertensive parents is higher .

It is estimated that the estimates of

Heritability apportion part of the population variance of BP to genetic factors , all BP variance represents a gene – by

Environment conditions . There are "no genes" for BP.

There are only "genes" predisposing to Rise in BP.

Most if not all the genetic component of Hypertension is expressed only in a permissive environment , so _ called context dependency [2,67]] .

Defining what environment factors promote and modify the expression of the genetic component Hypertension is as difficult as Identifying "Genes" for Hypertension , and most clues from cross _ cultural or case – control studies are not carefully measured ωhen population _ based genetic epidemiologic studies are PERFORMED.

For Individuals the greatest Relative Cardiovascular risk is associated with the Highest BP [8]. This correlation justifies the medical approach of Screening BP and treating Hypertensive Patients to reduce Individual risk.

However the distribution of Blood Pressure is Unimodal and the definition of Hypertension is 0perational [9,10]. Classifications such as Hypertensive and Normotensives are constantly changing [11,12] and do not necessarily differentiates Individuals in to meaningful biologic and therefore genetic groups.

Epidemiologic analysis indicate that the relationship between the Cardiovascular Disorders and the rise in Blood Pressure is continuous .

0BESITY AND HYPERTENSI0N:

0besity and Physical Inactivity are estimated to be Important Cause for the Cardiovascular Disorders . Excess weight gain increases the risk for Cardiovascular Disorders by Multiple Mechanisms .

The main factors are

Hypertension , Diabetes mellitus , Dyslipidemia , Atherosclerosis

Chronic Renal Dysfunction many of which are Independent [2-4]

This cluster of Disorders is 0ften referred to as "METABOLIC SYNDROME" , Although excess weight gain is the main cause for many of the patients .The relationship between the BMI , SBP & DBP are almost linear and have been 0bserved in diverse populations throughout the W0RLD . Metabolic Syndrome has the following conditions :

- **Obesity**
- **Increased BP**
- **Raised Fasting Glucose level in Blood**
- **Raised Serum Triglycerides level**

Reduced High Density Lipoprotein.

It is Increasingly associated with CVS Disorders and Diabetes Mellitus.

It is also called as "Syndrome X" , "Insulin Resistance Syndrome" , "Cardio Metabolic Syndrome_ , _Metabolic Syndrome X_ .

WHITE – COAT HYPERTENSION :

In treated Patients , the BP Increases in the Clinic or Hospital over Ambulatory BP and this has been termed the " White COAT Effect " or " White COAT Hypertension " [White Coat Phenomenon].

Advantages of Diagnosing White Coat Hypertension are :

- **Patients with White Coat Hypertension may not require drug therapy . Substantial Cost Saving occurs to the Patient .**
- **A Better diagnostic and prognostic tool risk assessment for individual patients may be possible .**
- **Clinical Drug Studies can exclude White – Coat Hypertension.**

HYPERTENSI0N AND ISCHEMIC HEART DISEASE :

Hypertension increases the risk of Ischemic Heart Diseases . Persons with Symptomatic Peripheral vascular Diseases (PVD) , have a 15 – fold increased rate of mortality from CVD and a high rate of concomitant

CAD and CVA [92] . Hypertension , Diabetes Mellitus and smoking are major risk factors for CAD .

It increases both the Morbidity and Mortality of the Patients .

NITRIC OXIDE :

Nitric Oxide originally described as Endothelium Derived Relaxing Factor (EDRF) is released from endothelium cells in response to shear , stress produced by blood flow and in response to activation of a variety of receptors .

NO is a free radical gas with an in vivo half life of a few seconds which is readily able to

cross biological membranes [5,6] .

The vascular Endothelium by synthesizing and releasing vasoactive substances plays a crucial role in the Pathogenesis of Hypertension .

Because 0f its position between Intraarterial pressure and smooth muscle cells responsible for peripheral resistance , the endothelium is thought to be both victim and 0ffender in arterial Hypertension .

HYPERTENSION

CARDIOVASCULAR RISK FACTORS AND

TARGET ORGAN DAMAGE

MAJOR RISK FACTORS :

- **Diabetes Mellitus**
- **Hypertension**
- **Obesity**
- **Alcohol**
- **Smoking**
- **Physical Inactivity**
- **Dyslipidemia**
- **Family history of Cardiovascular Disorder.**

TARGET ORGAN DAMAGE :

HEART :

1)Left Ventricular Hypertrophy

2)Angina Pectoris

3)Heart Failure.

BRAIN :

Stroke (Transient Ischemic Attack)

KIDNEY :

Chronic Kidney Disease

ARTERIES :

Peripheral Artery Disease .

EYE :

Retinopathy

CALCIUM CHANNEL BLOCKERS :

Calcium channel blockers (or)

Calcium channel Antagonists (or)

Calcium antagonists [51] are several medications that disrupt the movement of Calcium (Ca^{2+}) through Calcium Channels .

They are used as

Anti – Hypertensives drugs used to reduce Blood Pressure in Patients with Hypertension . They are particularly effective against large vessel stiffness (0ne of the common causes of elevated BP) in elderly patients [52] .

Voltage dependent Calcium

Channels are present in the Zona Glomerulosa of Human

Adrenal . It is of 3 types :

1)N Type 2) L Type 3) T Type

They can directly influence the Biosynthesis of Aldosterone in Adrenal Cortex cells , with consequent impact on the clinical treatment of Hypertension with these agents .

Voltage sensitive Calcium Channels (L – Type or slow channels) mediate the entry of extracellular Calcium into smooth muscles and cardiac myocytes , Sinoatrial Node (SA) and Atrioventricular Node (AV) in response to electrical depolarisation .

MECHANISM OF ACTION :

An Increased concentration of cytosolic

calcium causes increased contraction in both cardiac and vascular smooth muscle cells. The entry of extracellular calcium is Important in Initiating the contraction of cardiac myocytes calcium induced calcium release. The release of calcium from Intracellular storage sites also contribute to contraction of vascular smooth muscles particularly in some vascular beds.

Cytosolic calcium concentrations can be Increased by diverse contractile stimuli in Vascular Smooth Muscle cells.

CLASSES :

DIHYDRO PYRIDINE (DHP) :

Calcium Channel Blockers are derived from the Molecule Dihydro Pyridine .

NON _ DIHYDRO PYRIDINE :

PHENYL ALKYLAMINE

Phenyl Alkylamine Calcium Channel Blockers are relatively selective for Myocardium . It reduces the Myocardial Oxygen Demand and reverse Coronary Spasm and are used to treat Angina .

They have minimal vasodilatory effects compared with dihydropyridine and therefore cause less reflex " tachycardia" making it appealing for treatment

of "Angina" . Where "Tachycardia " can be the most significant contributor to the heart's need for 0xygen .

BENZOTHIAZEPINE :

Benzothiazepine Calcium Channel Blockers belong to the Benzothiazepine class of compounds and are an Intermediate class between Phenylalkylamine and Dihydropyridine in their selectivity for vascular calcium channels.

NON – SELECTIVE :

While most of the agents are relatively selective there are additional agents that are considered non – selective . These include mibe fradil , bepridil , flunarizine (BBB crossing) [53] , fluspirilene (BBB Crossing)

AMLODIPINE :

It belongs to dihydro pyridine type Calcium Channel Blockers [54,55] .

FORMULA :

$C_{20}H_{25}Cl\ N_2\ 0_5$

MOLECULAR MASS :

4O8.87 grams/mol

SYSTEMIC NAME : (IUPAC NAME)

RS – 3 ethyl 5 – methyl 2 – [(2 – aminoethoxy) methyl] – 4 – (2- chlorophenyl) _ 6 _ methyl - 1 , 4 – dihydropyridine -3 , 5 _ dicarboxylate

MECHANISM OF ACTION :

Amlodipine inhibits calcium into vascular smooth muscle cells and cardiac muscle cells . The contractile process depends upon the movement of calcium

ions in to the cells.

It inhibits calcium influx across cell membranes selectively .

METABOLISM :

It is absorbed 0rally with mean 0ral bioavailabilty around 6O% . It is metabolised in the liver. The half – life is about 30 – 5O hours and steady state plasma concentrations are achieved after 7-8 days of daily dosing . Renal Excretion is the major R0UTE of excretion with about 6O% of an administered D0SE recoverd in urine largely an inactive pyridine METAB0LITE .

ADVERSE EFFECTS :

1)COMMON :

Peripheral oedema and fatigue

2)LESS COMMON :

Blood disorders , development of breasts in men , impotence , depression , insomnia , tachycardia gingival enlargement.

CONTRA INDICATIONS :

Breast feeding , Cardiogenic Shock , Unstable Angina , SBP & DBP below 9O/6O mmhg , Aortic Stenosis .

DOSAGE :

2.5 mg , 5 mg , 1O mg doses once daily.

CILNIDIPINE :

Cilnidipine is a 4 th Generation Calcium Channel Antagonist accompanied with L – Type and N - Type calcium channel blocking function . It dilates both arterioles and venules so that it reduces the capillary bed pressure .

F0RMULA :

$C_{27} H_{28} N_2 0_7$.

M0LECULAR MASS :

492.52 grams/mol

SYSTEMIC NAME : (IUPAC NAME)

3-[E]-3-Phenyl-2-propenyl 5-2-methoxyethyl 2,6-dimethyl -4-[m-nitrophenyl]-1,4-dihydropyridine-3,5-dicaboxylate

MECHANISM :

It suppresses the L – Type and N – Type Calcium channels found on peripheral sympathetic nerve endings which control nor-adrenaline release . N – Type channels controls the veins and venules (α_1 adrenoceptors)[56] .

METAB0LISM :

METAB0LISM Occurs in Liver .

EXCRETI0N :

It is excreted in Urine .

LEPTIN :

Cilnidipine reduces leptin in patients (leptin is an important link between obesity and metabolic syndrome[57]

Cilnidipine suppresses the cardiac sympathetic activity [58] . It causes resolution of amlodipine induced edema while maintaining adequate control of BP [59] .It improves the condition of the patient with CKD who are already on RAAS inhibitors[60] .

S.no	Group	Name	Age	Sex	Sys.BP	Dia.BP
1	Cilnidipine	Lakshmi	60	2	126	82
2	Cilnidipine	Ishwaria	22	2	130	90
3	Cilnidipine	Raniraju	37	2	124	84
4	Cilnidipine	Saraswathy	24	2	126	80
5	Cilnidipine	Malathy	27	2	123	83
6	Cilnidipine	Abitha	55	2	126	86
7	Cilnidipine	Chandra	50	2	124	86
8	Cilnidipine	Ezhumalai	65	1	130	90
9	Cilnidipine	Lakshmi	50	2	128	82
10	Cilnidipine	Lakshmana	60	1	132	86
11	Cilnidipine	Kamala	65	2	128	86
12	Cilnidipine	Aravalli	50	2	126	82
13	Cilnidipine	Elumalai	40	1	124	82
14	Cilnidipine	Ettiyammal	33	2	130	92
15	Cilnidipine	Panchalai	60	2	132	92
16	Cilnidipine	Govindammal	66	2	120	82
17	Cilnidipine	Kalavathy	60	2	132	86
18	Cilnidipine	Sundramoorthy	70	1	136	82
19	Cilnidipine	Thowsinisha	46	2	128	92
20	Cilnidipine	Anjalai	70	2	120	80
21	Cilnidipine	ranjani	55	2	126	86
22	Cilnidipine	devi	50	2	124	86
23	Cilnidipine	kamatchi	60	2	132	92
24	Cilnidipine	Barathiyar	70	1	136	82
25	Cilnidipine	munusamy	45	1	124	80
26	Cilnidipine	renuga	22	2	130	90
27	Cilnidipine	poonkodi	37	2	124	84
28	Cilnidipine	sivasankari	65	2	128	86
29	Cilnidipine	rajalakshmi	27	2	122	83
30	Cilnidipine	mariappan	35	1	124	80
31	Cilnidipine	manjula	50	2	124	86
32	Cilnidipine	baskar	42	1	120	82
33	Cilnidipine	raniyamma	50	2	128	82
34	Cilnidipine	meenkshi	39	2	122	80
35	Cilnidipine	rajakumar	47	1	120	80
36	Cilnidipine	kumaresan	65	1	130	90
37	Cilnidipine	rani	46	2	128	92
38	Cilnidipine	shanmugam	60	1	130	80
39	Cilnidipine	periyanayaki	55	2	126	86
40	Cilnidipine	parasu	39	1	120	82
41	Cilnidipine	saranya	24	2	126	80
42	Cilnidipine	sivaranjani	41	2	124	86
43	Cilnidipine	ramajeyam	60	1	132	86
44	Cilnidipine	lakshmi	60	2	123	82
45	Cilnidipine	gokul	47	1	130	80
46	Cilnidipine	paruvathy	39	2	130	84

47	Cilnidipine	parimala	31	2	132	86
48	Cilnidipine	rajasekaran	65	1	122	90
49	Cilnidipine	anthoniyar	34	1	120	80
50	Cilnidipine	rajee	41	2	126	82
1	Amlodipine	sadaiyandi	40	1	136	98
2	Amlodipine	krishnaveni	60	2	132	92
3	Amlodipine	Yasoda	40	2	140	100
4	Amlodipine	Beevjohan	75	2	138	92
5	Amlodipine	Seluthiyan	45	1	136	98
6	Amlodipine	Dhanabakkiyam	75	2	138	96
7	Amlodipine	Alangaram	70	2	142	98
8	Amlodipine	Thangamani	50	1	136	98
9	Amlodipine	Palani	60	1	138	96
10	Amlodipine	Kasi	65	1	148	92
11	Amlodipine	Rani	60	2	143	92
12	Amlodipine	Jaya	51	2	146	98
13	Amlodipine	Kanniappan	80	1	140	92
14	Amlodipine	Jaya	50	2	130	98
15	Amlodipine	Mohammed Abhi	67	1	140	100
16	Amlodipine	Kamatchi	60	2	136	98
17	Amlodipine	Lakshmi	70	2	132	92
18	Amlodipine	Rajam	51	2	140	100
19	Amlodipine	Kanniappan	85	1	138	92
20	Amlodipine	Govindan	65	1	140	100
21	Amlodipine	Thirumalai	65	1	138	92
22	Amlodipine	Varadarajan	82	1	138	96
23	Amlodipine	Naygamary	45	2	130	90
24	Amlodipine	renuga	38	2	128	80
25	Amlodipine	pandu	67	1	140	100
26	Amlodipine	rangan	43	1	130	80
27	Amlodipine	subashini	60	2	136	98
28	Amlodipine	siva	62	1	126	80
29	Amlodipine	basha	49	1	142	80
30	Amlodipine	nirmala	51	2	140	100
31	Amlodipine	suburamani	70	1	130	70
32	Amlodipine	rajagopal	67	1	134	92
33	Amlodipine	sulochana	60	2	143	110
34	Amlodipine	maduvanthy	29	2	140	100
35	Amlodipine	ranganayaki	50	2	135	98
36	Amlodipine	rathika	36	2	126	80
37	Amlodipine	sampath	51	1	130	70
38	Amlodipine	muthayya	80	1	140	92
39	Amlodipine	poomika	31	2	126	70
40	Amlodipine	rakalai	85	1	138	92
41	Amlodipine	kavitha	35	2	124	70
42	Amlodipine	velamma	60	2	136	98
43	Amlodipine	visalatchi	48	2	134	80

44	Amlodipine	amutha	53	2	130	90
45	Amlodipine	prema	51	2	146	98
46	Amlodipine	duraisamy	65	1	148	90
47	Amlodipine	pandiyan	28	1	132	92
48	Amlodipine	ramani	32	2	140	100
49	Amlodipine	kothaiyamma	70	2	132	92
50	Amlodipine	malathy	51	2	140	100

BMI	Sodium	Creatinine	Pottasium	SGPT
19.23	135	0.7	3.6	7
20.13	136	0.7	3.7	8
21.22	137	0.8	3.8	32
19.3	137	0.8	3.5	38
21.22	136	1.2	3.6	39
23.33	135	1.1	3.7	40
24.35	134	1	3.8	41
25	140	1.1	3.9	40
19.2	139	1	4	8
20.21	137	0.9	4.1	32
21.23	138	0.8	4.2	35
22.23	140	0.9	5	36
24.25	145	1	4.8	38
25	142	1.2	4.6	40
26	141	1.3	4.5	41
25	140	1.2	4.4	42
24.33	139	1.1	4.3	53
25.33	140	1	4.2	54
25	142	0.8	4.1	55
24.33	143	1.1	4	56
23.33	135	1.1	3.7	40
24.35	134	1	3.8	41
26	141	1.3	4.5	41
25.33	140	1	4.2	54
25	140	1.2	4.1	41
20.13	136	0.7	3.7	8
21.22	137	0.8	3.8	32
21.23	138	0.8	4.2	35
21.22	136	1.2	3.6	39
20	138	0.8	4.2	35
24.35	134	1	3.8	41
21	140	1.2	4.1	41
19.2	139	1	4	8
23	136	0.7	3.7	8
20	137	0.8	3.8	32
25	140	1.1	3.9	40
25	142	0.8	4.1	55
22	133	1.2	4	30
23.33	135	1.1	3.7	40
20.8	140	1	3.5	35
19.3	137	0.8	3.5	38
21.3	134	0.8	4.2	40
20.21	137	0.9	4.1	32
19.9	142	0.8	4.1	55
22.23	140	0.9	5	36
21	134	1.1	4.8	38

25	142	1.2	4.6	40
22.2	139	1.1	4.3	53
19.5	138	1	3.4	18
24.25	145	1	3.8	22
26	135	0.8	4	38
25	143	1	4.1	38
25.3	142	1.1	4.3	42
24.38	140	1.2	4.3	41
25.22	139	1.3	4.4	40
25.33	140	1.2	4.5	38
26.3	141	1.1	4.6	34
25.33	142	1	4.8	27
26	145	0.9	4.9	26
25	138	0.8	5	21
24.33	139	0.7	5.1	22
25	137	0.8	5.2	38
26	140	1	5.3	40
25.33	134	1.1	5.4	50
26.33	135	1.2	5	51
26.73	136	1.3	5.1	52
28	137	1.2	5.2	53
27	136	0.9	5.3	54
27.33	135	1.1	5	55
28.03	136	1.2	5	56
26	140	1	4.8	34
26.35	136	1	5.3	40
22.4	134	1.1	5.4	50
24.33	139	0.7	5.1	22
26.33	140	0.8	4.6	30
28.1	134	1.2	4.9	48
26.73	138	0.9	5.2	32
22	140	1.3	5.1	44
27	135	1.2	5	51
27.5	136	0.9	5.3	54
24.6	140	1.1	4.8	38
21.7	132	1	4.9	44
25.9	136	1.3	5.1	52
24.7	130	0.8	3.5	48
25.33	134	1.1	5.4	50
26.2	132	1.3	3.9	52
24	136	1.3	5.1	52
26	135	1.2	5	51
25.9	140	1	4.3	50
27.33	135	1.1	5	55
27.1	137	0.8	5.2	38
26.73	140	1	5.3	40
23.8	**138**	0.9	4.1	42

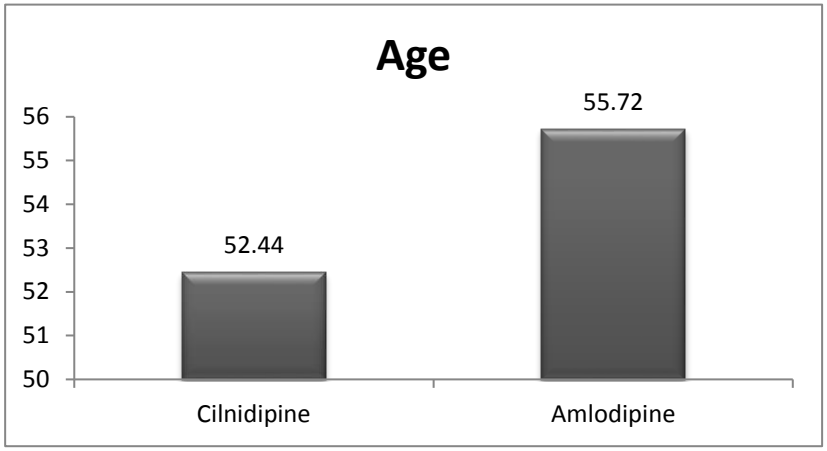
27.4	136	0.9	5.3	36
25	136	1.3	5.1	38
23.4	140	1	3.9	40
25	138	0.8	5	21
22.9	140	1.3	3	45
28	137	1.2	5.2	53
27	136	0.9	5.3	54

Variable	Group	N	Mean	td. Deviatio	t	p value
Age	Cilnidipine	50	52.44	8.709	1.99	0.05
	Amlodipine	50	55.72	7.749		
Variable	**Group**	**N**	**Mean**	**td. Deviatio**	**t**	**p value**
Sys.BP	Cilnidipine	50	126.56	4.214	9.721	**0.0001**
	Amlodipine	50	136.42	5.803		
Variable	**Group**	**N**	**Mean**	**td. Deviatio**	**t**	**p value**
Dia.BP	Cilnidipine	50	84.6	3.897	5.261	**0.0001**
	Amlodipine	50	92.04	9.209		
Variable	**Group**	**N**	**Mean**	**td. Deviatio**	**t**	**p value**
BMI	Cilnidipine	50	22.4454	2.20299	8.43	**0.0001**
	Amlodipine	50	25.6534	1.54509		
Variable	**Group**	**N**	**Mean**	**td. Deviatio**	**t**	**p value**
Sodium	Cilnidipine	50	136.04	3.077	2.237	**0.028**
	Amlodipine	50	137.4	3.003		
Variable	**Group**	**N**	**Mean**	**td. Deviatio**	**t**	**p value**
Creatinine	Cilnidipine	50	0.904	0.147	4.323	**0.0001**
	Amlodipine	50	1.046	0.1798		
Variable	**Group**	**N**	**Mean**	**td. Deviatio**	**t**	**p value**
Pottasium	Cilnidipine	50	4.04	0.3912	8.492	**0.0001**
	Amlodipine	50	4.832	0.5309		
Variable	**Group**	**N**	**Mean**	**td. Deviatio**	**t**	**p value**
SGPT	Cilnidipine	50	36.06	13.157	2.713	**0.008**
	Amlodipine	50	42.4	9.992		

	Group	N	Mean	Std. Deviation	Std. Error Mean	t	p value
Age	Cilnidipine	50	52.44	8.709	1.232	1.99	0.05
	Amlodipine	50	55.72	7.749	1.096		
Sys.BP	Cilnidipine	50	126.56	4.214	0.596	9.721	**0.0001**
	Amlodipine	50	136.42	5.803	0.821		
Dia.BP	Cilnidipine	50	84.6	3.897	0.551	5.261	**0.0001**
	Amlodipine	50	92.04	9.209	1.302		
BMI	Cilnidipine	50	22.4454	2.20299	0.31155	8.43	**0.0001**
	Amlodipine	50	25.6534	1.54509	0.21851		
Sodium	Cilnidipine	50	136.04	3.077	0.435	2.237	**0.028**
	Amlodipine	50	137.4	3.003	0.425		
Creatinine	Cilnidipine	50	0.904	0.147	0.0208	4.323	**0.0001**
	Amlodipine	50	1.046	0.1798	0.0254		
Pottasium	Cilnidipine	50	4.04	0.3912	0.0553	8.492	**0.0001**
	Amlodipine	50	4.832	0.5309	0.0751		
SGPT	Cilnidipine	50	36.06	13.157	1.861	2.713	**0.008**
	Amlodipine	50	42.4	9.992	1.413		

Sex	Group 1	Group 2	Total	Chi Sq	P
Male	16	22	38	0.303	0.1
Female	34	28	62		
Total	50	50	100		

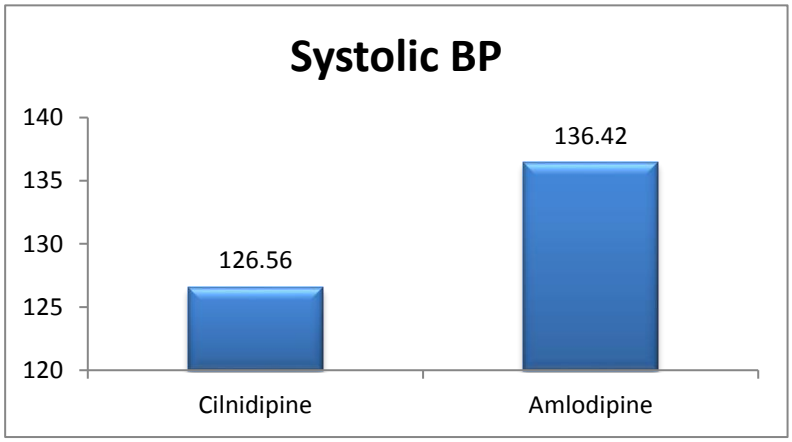
	Age
Cilnidipine	52.44
Amlodipine	55.72



	Systolic BP
Cilnidipine	126.56
Amlodipine	136.42

	Diastolic BP
Cilnidipine	84.6
Amlodipine	92.04

	Sodium
Cilnidipine	136.04
Amlodipine	137.4



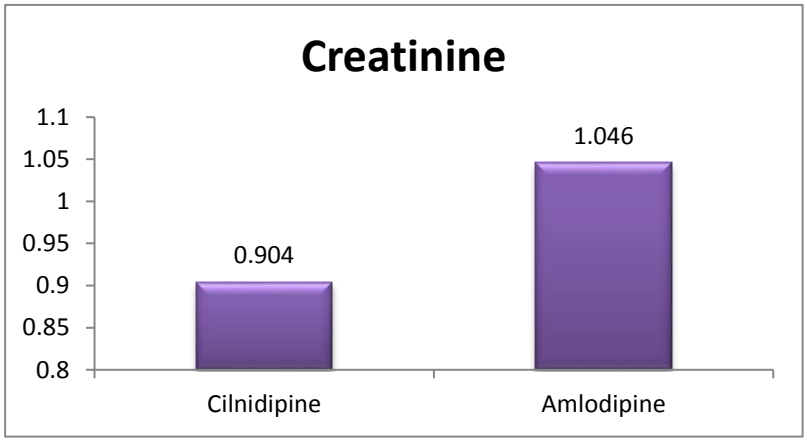
	Creatinine
Cilnidipine	0.904
Amlodipine	1.046

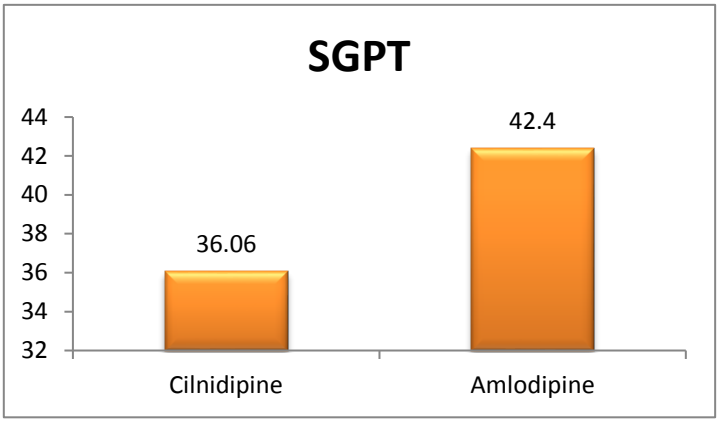
	Pottasium
Cilnidipine	4.04
Amlodipine	4.832

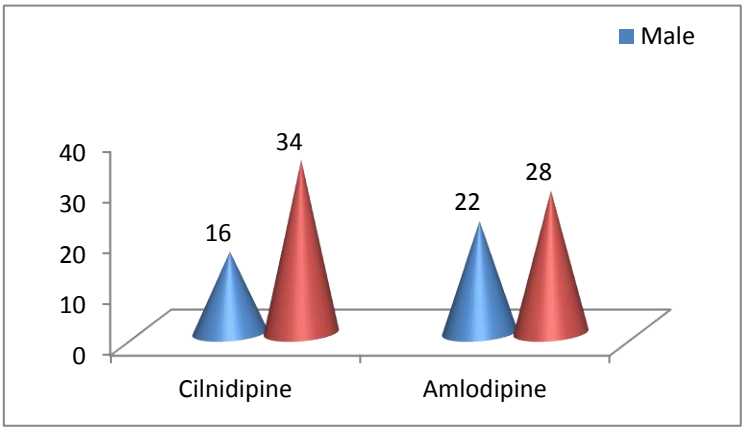
	SGPT
Cilnidipine	36.06
Amlodipine	42.4

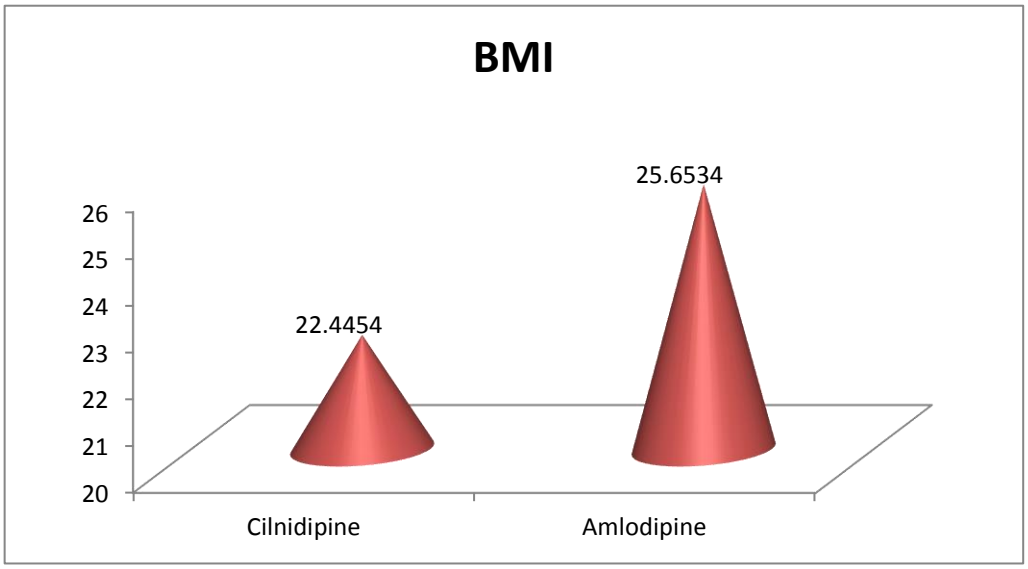
	BMI
Cilnidipine	22.4454
Amlodipine	25.6534

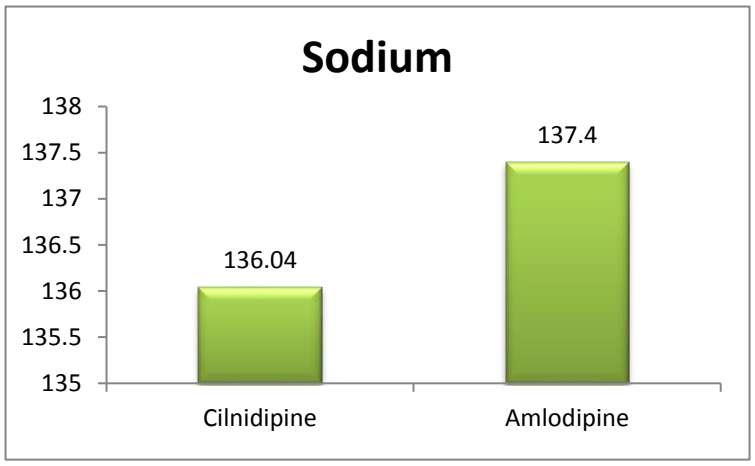
Sex	Cilnidipine	Amlodipine
Male	16	22
Female	34	28

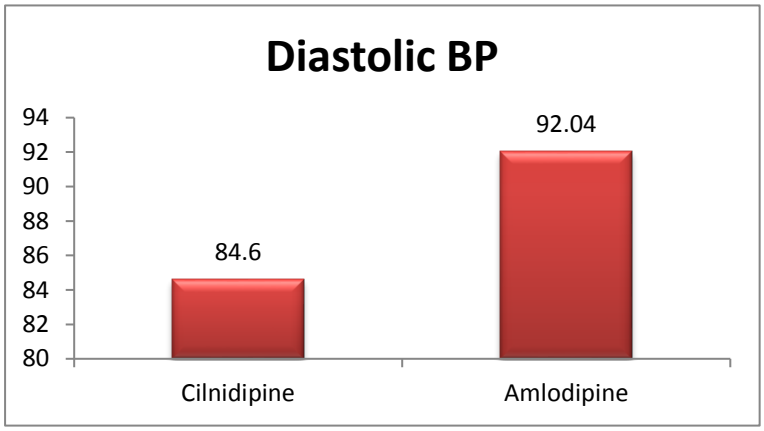


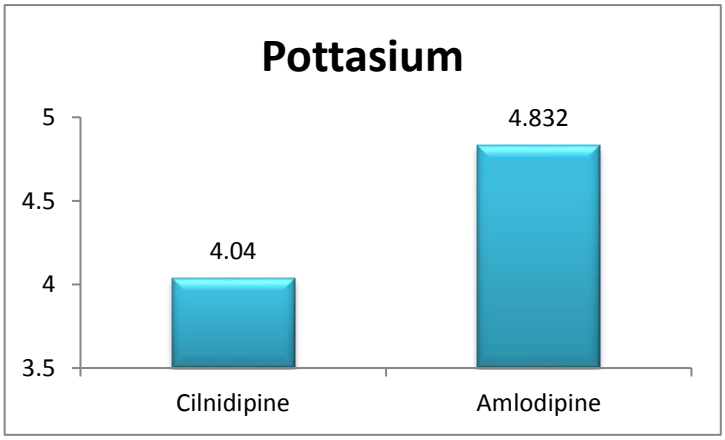

SGPT
44
42
40
38
36
34
32
36.06
42.4
Cilnidipine
Amlodipine


Male
40
30
20
10
0
16
34
22
28
Cilnidipine
Amlodipine

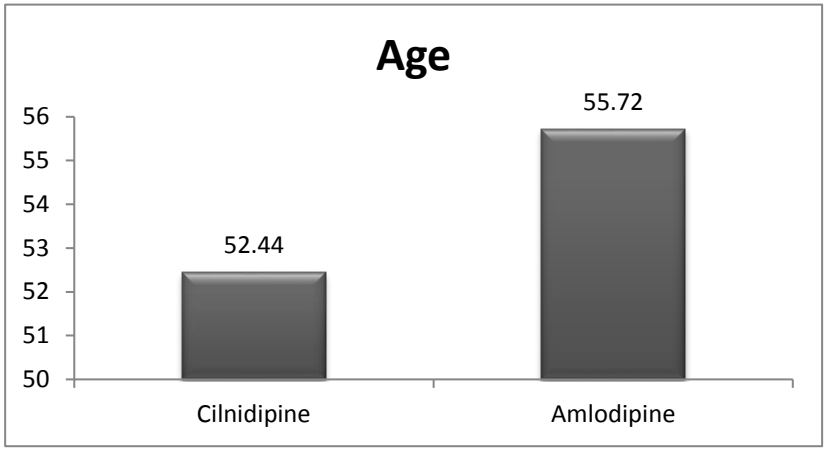

BMI
26
25
24
23
22
21
20
22.4454
25.6534
Cilnidipine
Amlodipine


Sodium
138
137.5
137
136.5
136
135.5
135
136.04
137.4
Cilnidipine
Amlodipine


Diastolic BP
94
92
90
88
86
84
82
80
84.6
92.04
Cilnidipine
Amlodipine


Pottasium
5
4.5
4
3.5
4.04
4.832
Cilnidipine
Amlodipine

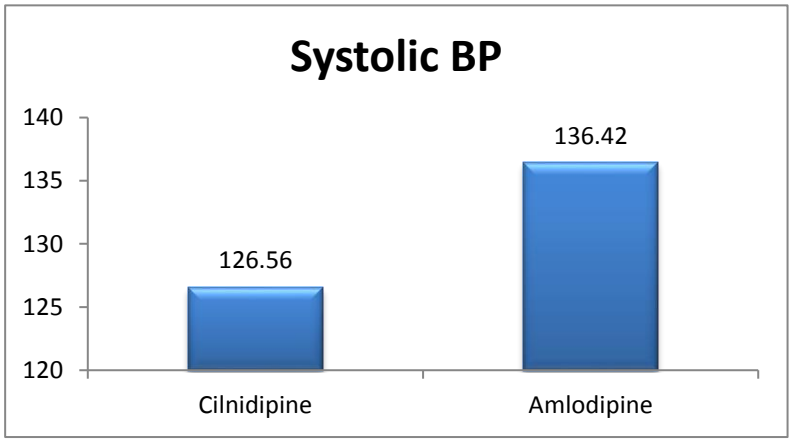
	Age
Cilnidipine	52.44
Amlodipine	55.72



	Systolic BP
Cilnidipine	126.56
Amlodipine	136.42

	Diastolic BP
Cilnidipine	84.6
Amlodipine	92.04

	Sodium
Cilnidipine	136.04
Amlodipine	137.4

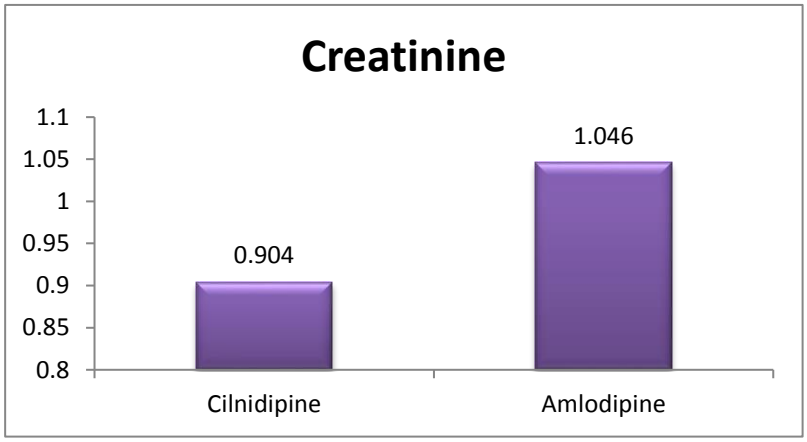


	Creatinine
Cilnidipine	0.904
Amlodipine	1.046

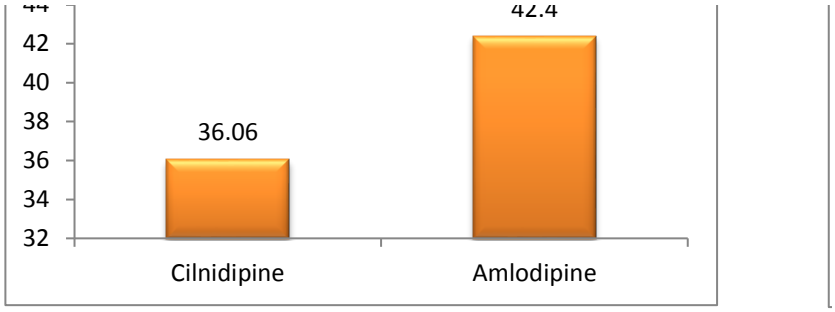
	Pottasium
Cilnidipine	4.04
Amlodipine	4.832

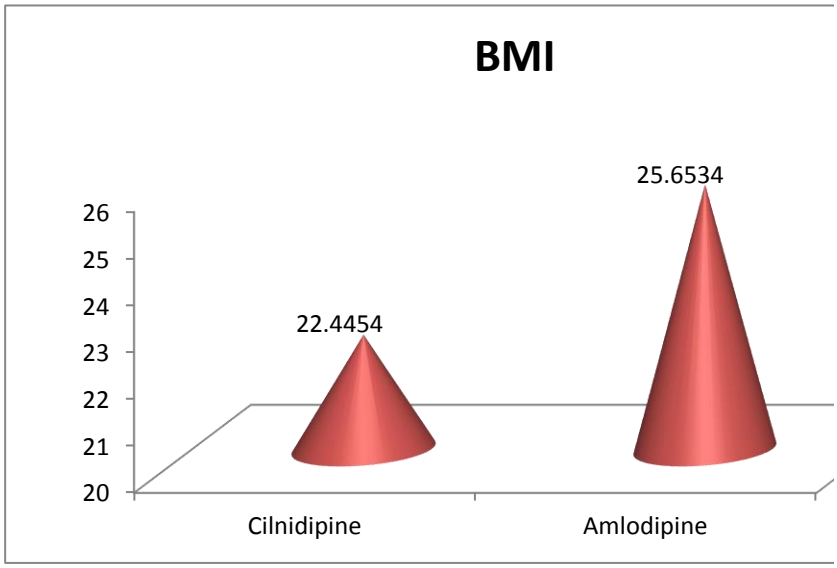
	SGPT
Cilnidipine	36.06
Amlodipine	42.4

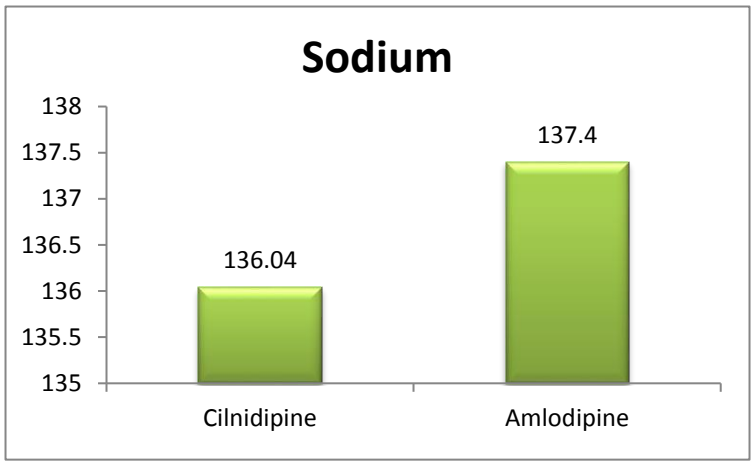
	BMI
Cilnidipine	22.4454
Amlodipine	25.6534

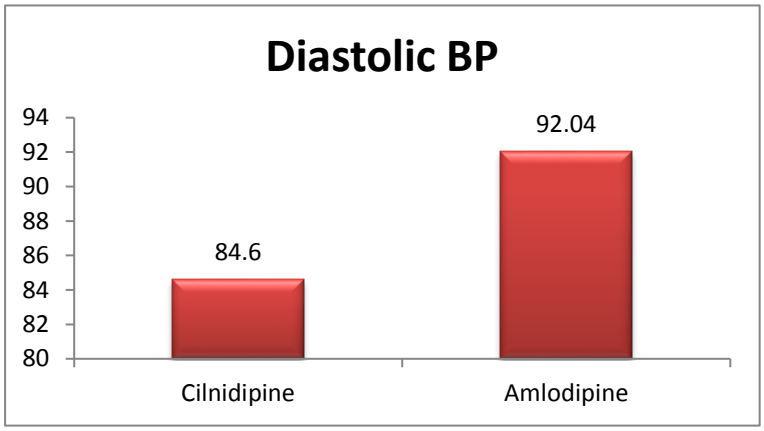


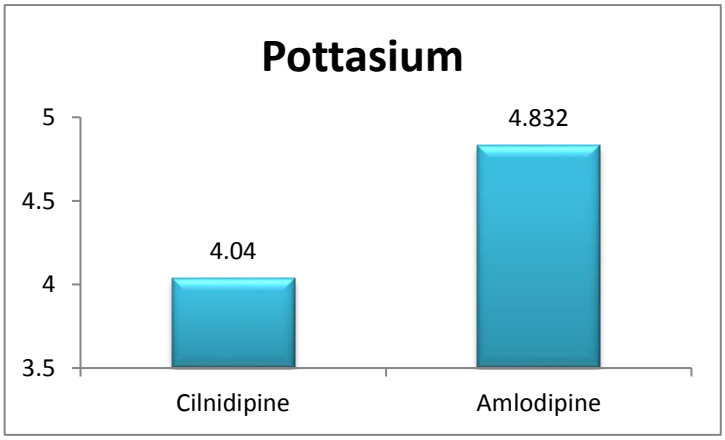
Sex	Cilnidipine	Amlodipine
Male	16	22
Female	34	28


42.4
42
40
38
36.06
36
34
32
Cilnidipine
Amlodipine

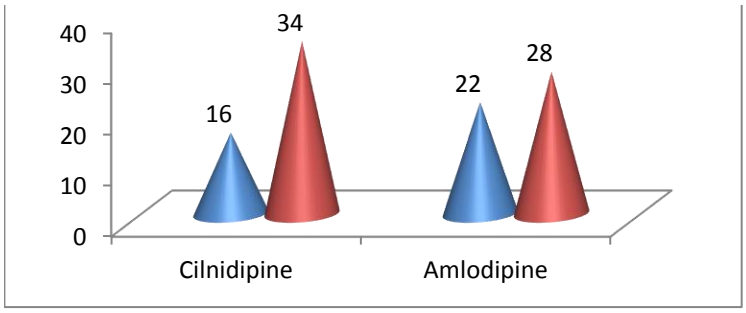

BMI
25.6534
26
25
24
22.4454
23
22
21
20
Cilnidipine
Amlodipine


Sodium
138
137.5
137
136.5
136
135.5
135
136.04
137.4
Cilnidipine
Amlodipine


Diastolic BP
94
92
90
88
86
84
82
80
84.6
92.04
Cilnidipine
Amlodipine


Pottasium
5
4.5
4
3.5
4.04
4.832
Cilnidipine
Amlodipine


Male

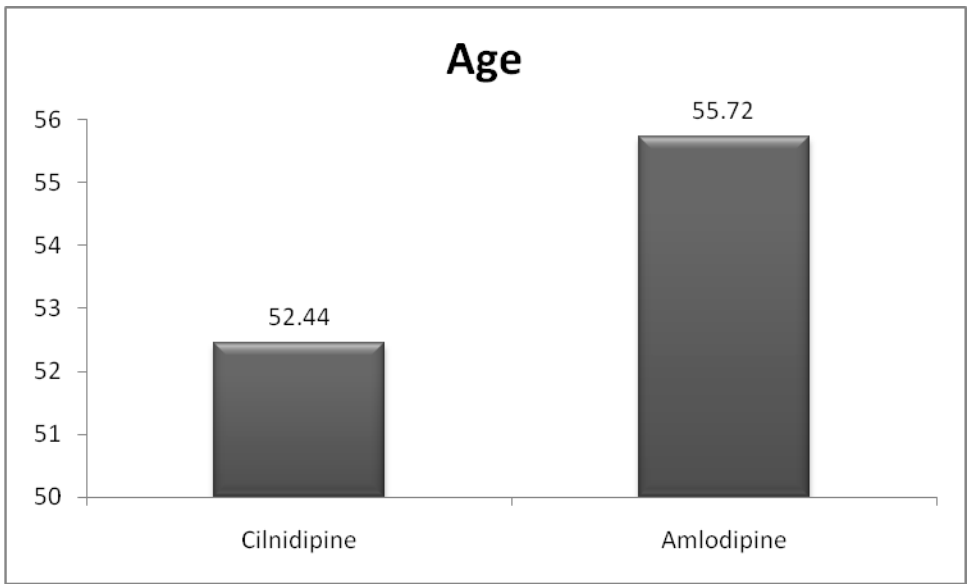

40
30
20
10
0
34
16
28
22
Cilnidipine
Amlodipine

Results:-

- There is no significant difference between two drugs for age (t test) & sex (chi sq test)
- There is significant diff b/w 2 grps – all other variables (Student t test)

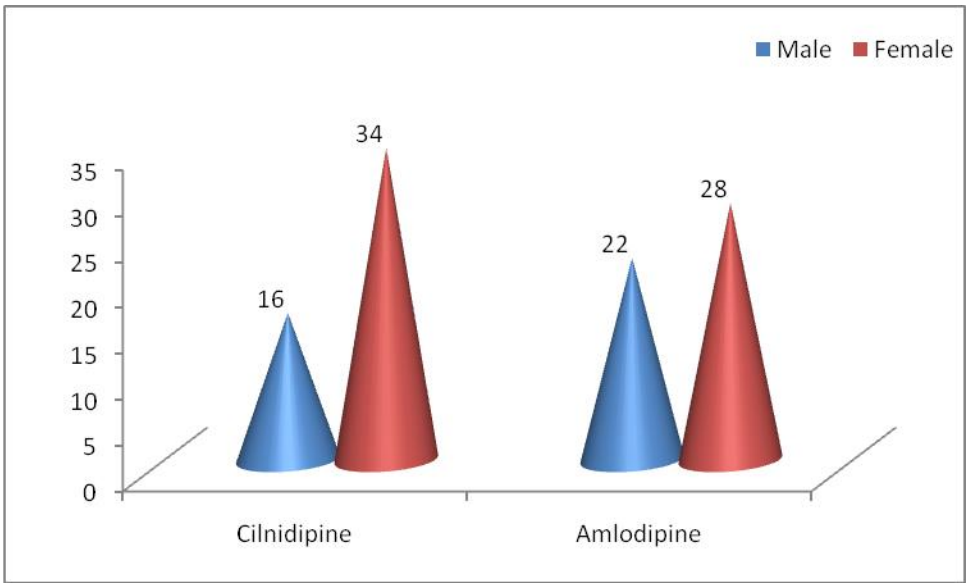
1. Age Distribution: -

Variable	Group	N	Mean	Std. Deviation	t	p value
Age	Cilnidipine	50	52.44	8.709	1.99	0.05
	Amlodipine	50	55.72	7.749		



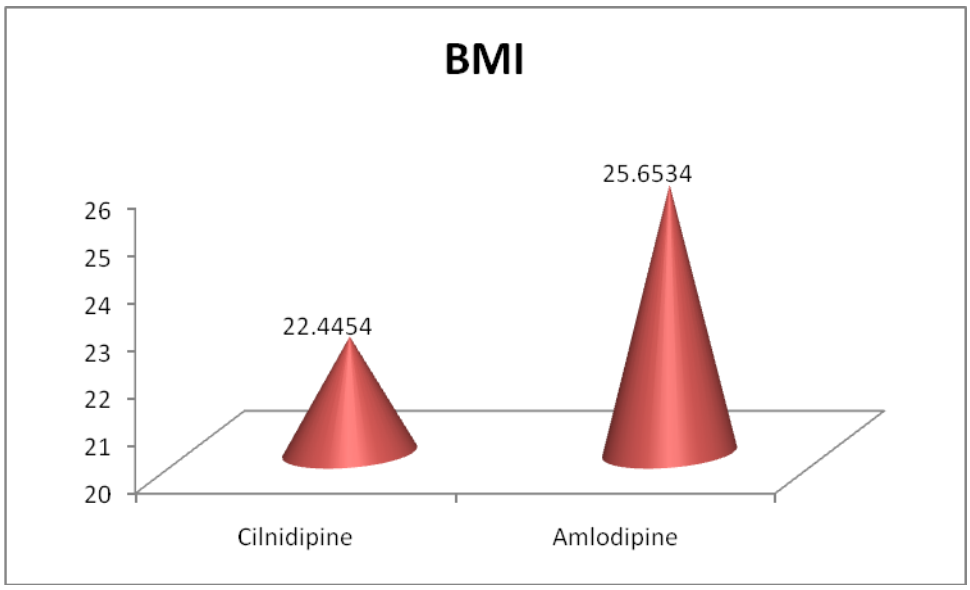
2. Sex Distribution: -

Sex	Group 1	Group 2	Total	Chi Sq	P
Male	16	22	38	0.303	0.1
Female	34	28	62		
Total	50	50	100		



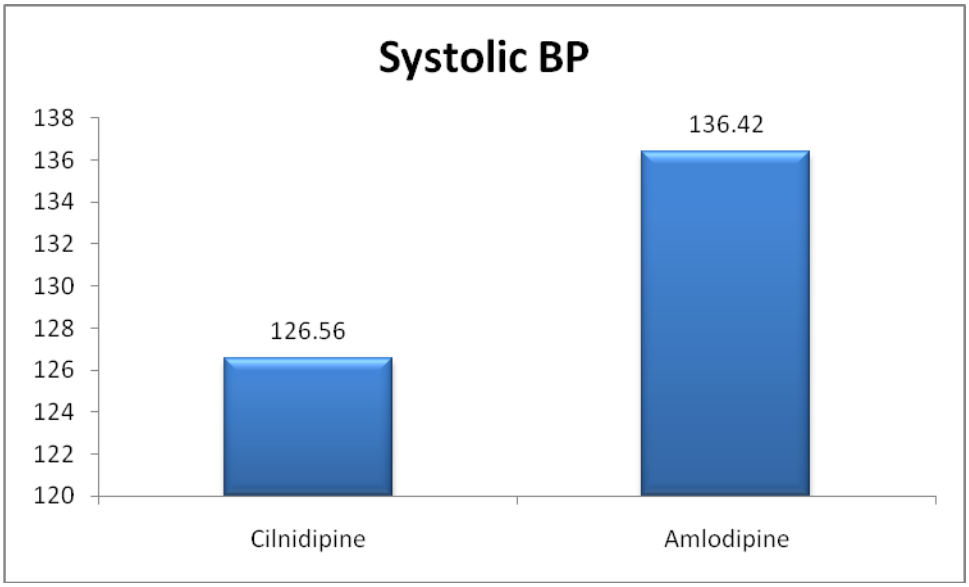
3. Comparison of BMI:-

Variable	Group	N	Mean	Std. Deviation	t	p value
BMI	Cilnidipine	50	22.4454	2.20299	8.43	**0.0001**
	Amlodipine	50	25.6534	1.54509		



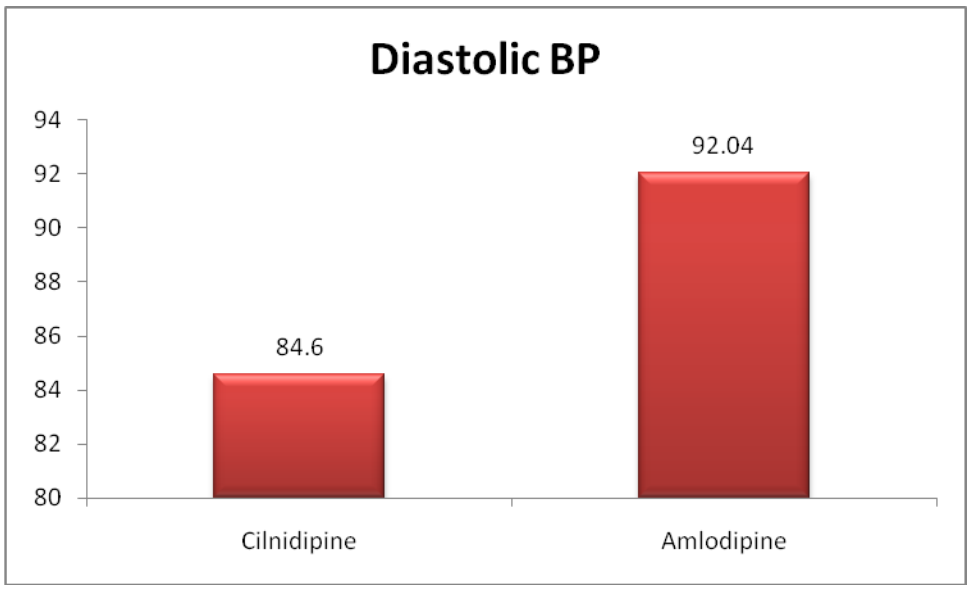
4. Comparison of Systolic Blood Pressure among study groups

Variable	Group	N	Mean	Std. Deviation	T	p value
Sys.BP	Cilnidipine	50	126.56	4.214	9.721	**0.0001**
	Amlodipine	50	136.42	5.803		



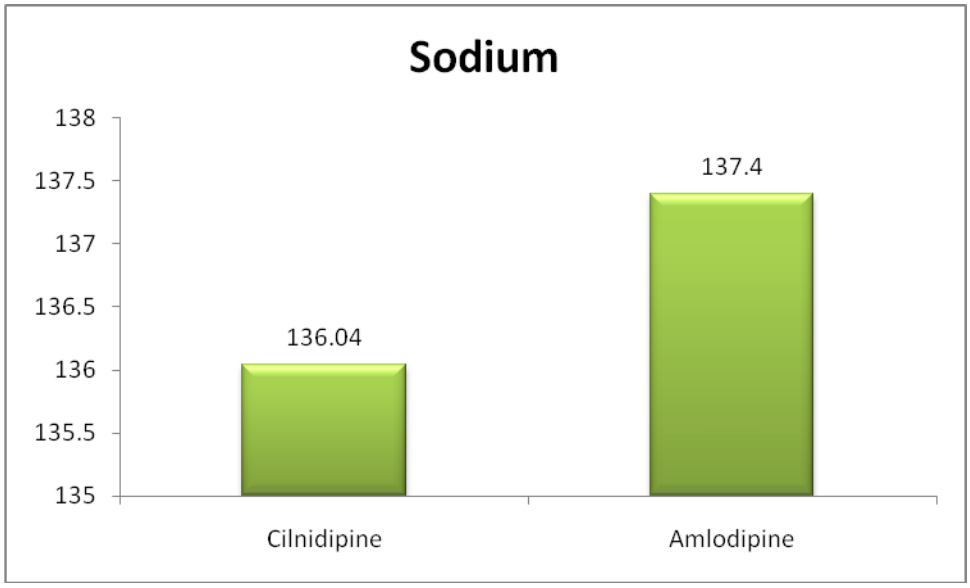
5. Comparison of Systolic Blood Pressure among study groups

Variable	Group	N	Mean	Std. Deviation	T	p value
Dia.BP	Cilnidipine	50	84.6	3.897	5.261	**0.0001**
	Amlodipine	50	92.04	9.209		



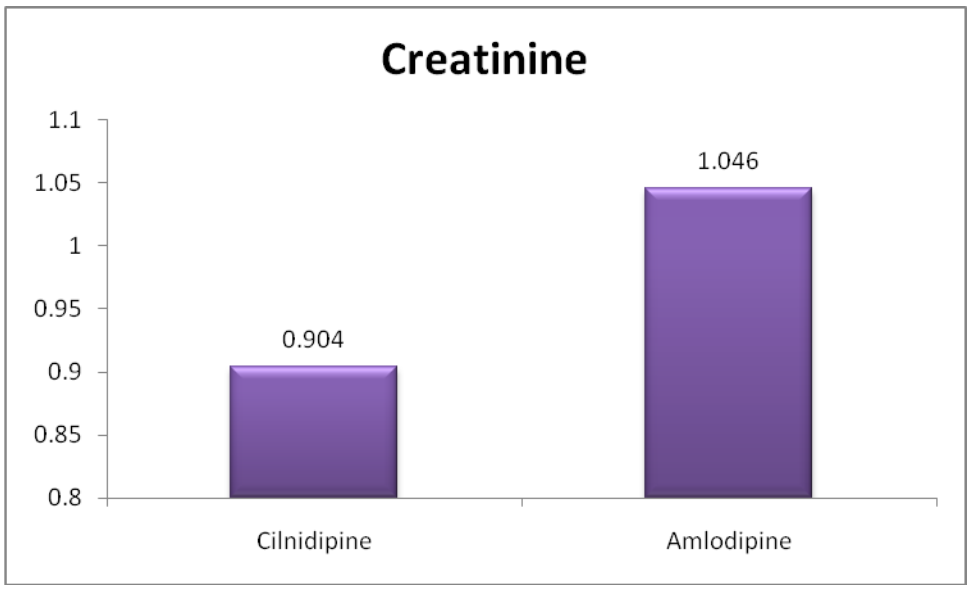
6. Comparison of Systolic Blood Pressure among study groups

Variable	Group	N	Mean	Std. Deviation	t	p value
Sodium	Cilnidipine	50	136.04	3.077	2.237	**0.028**
	Amlodipine	50	137.4	3.003		



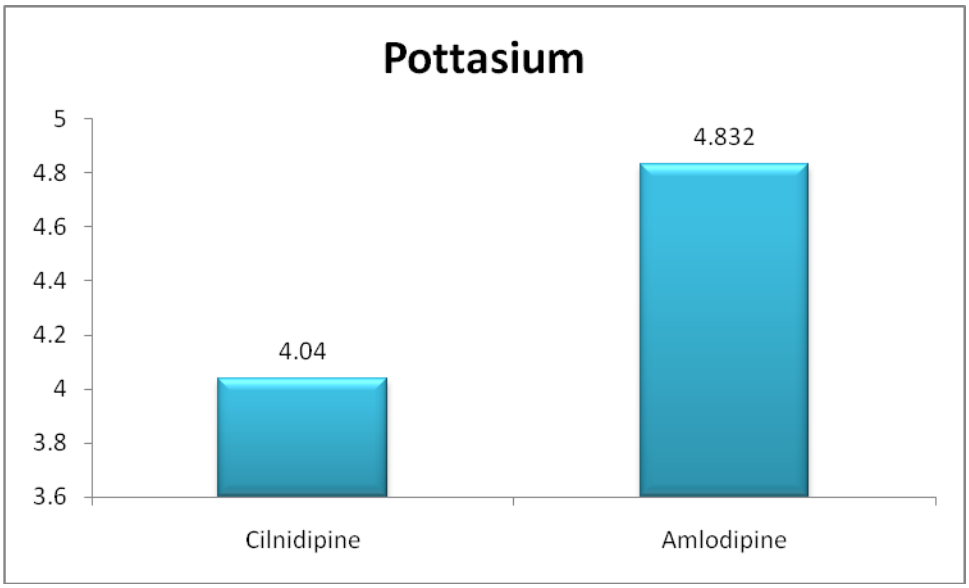
7. Comparison of Systolic Blood Pressure among study groups

Variable	Group	N	Mean	Std. Deviation	t	p value
Creatinine	Cilnidipine	50	0.904	0.147	4.323	**0.0001**
	Amlodipine	50	1.046	0.1798		



8. Comparison of Systolic Blood Pressure among study groups

Variable	Group	N	Mean	Std. Deviation	t	p value
Pottasium	Cilnidipine	50	4.04	0.3912	8.492	**0.0001**
	Amlodipine	50	4.832	0.5309		



9. Comparison of Systolic Blood Pressure among study groups

Variable	Group	N	Mean	Std. Deviation	t	p value
SGPT	Cilnidipine	50	36.06	13.157	2.713	**0.008**
	Amlodipine	50	42.4	9.992